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GOVERNOR

STATE OF MAINE
DEPARTMENT OF HUMAN SERVICES
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AUGUSTA, ME 04333-0011

February 3, 2004

TO: Interested Parties

FROM: Christine Zukas-Lessard, Acting Director, Bureau of Medical Services

SUBJECT: Emergency Rule: Chapter 104, Maine Drugs for the Elderly Benefit

This letter gives notice of adoption of Department of Human Services emergency rule changes, which will be in effect for 90 days. Pursuant to 5 MRSA Sec. 8054 the Department of Human Services has determined that immediate adoption of these rules is necessary to avoid an immediate threat to public health, safety or general welfare. The threat to the public health, safety or general welfare has become clear from recent financial information gathered by the Department and by the analysis of that information conducted by the Department of Administrative and Financial Services ("DAFS"). That financial information and analysis reveals that, absent immediate corrective action, the funding available to the Department would soon be inadequate to meet various expenditures of the Department, threatening both members and providers in the MaineCare and DEL programs.

This rule is necessary in order reduce Department costs so as to continue administration of the Maine Drugs for the Elderly pharmacy benefits that are critical to the health and well-being of certain eligible elderly and disabled residents of the State of Maine. These persons are not otherwise eligible for comparable benefits under any other program.

The Department will reimburse drugs to pharmacy providers at the lowest of 1) the usual and customary charge; or 2) AWP minus 15% (plus a $2.35 professional fee), or 3) the Maine maximum allowable cost (plus a $2.35 professional fee). Previous to the adoption of this emergency rule, the second of the three preceding options was "AWP minus 14%, plus a $2.35 professional fee." These rules will save an estimated $135,925 of State funds in SFY '04, determined necessary to preserve the DEL benefit.

The Department will propose rules through the regular APA process in the near future that reflect these changes. A public hearing will be scheduled as part of the regular rulemaking process.

Interested parties may obtain a full copy of the emergency rule changes from the Bureau of Medical Services website at http://www.state.me.us/bms/rulemaking/. Locate Emergency rules- Chapter 104, Section 2, and click on the document symbol to download the file.

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SECTION 2 MAINE DRUGS FOR THE ELDERLY BENEFIT 9-29-03

2.01 AUTHORITY

The Maine Drugs for the Elderly Benefit, also referred to as the Maine Low Cost Drugs for the Elderly or Disabled (DEL) Benefit, is authorized by, and these regulations are issued under, the authority of 22 M.R.S.A. §254. The Commissioner of the Department of Human Services has delegated the responsibility for administration of the Benefit to the Bureau of Medical Services.

2.02 DEFINITIONS

2.02-1 Covered Drug is a drug for which the Department reimburses under the DEL Benefit. See Subsection 2.05 of this Section.

2.02-2 DEL Rebate Agreement is an agreement between the Department and a drug manufacturer that provides that the drug manufacturer will make rebate payments for both the basic and supplemental components of the Benefit.

2.02-3 Drug Utilization Review (DUR) means a process designed to ensure that prescriptions are appropriate, medically necessary, cost-effective, and not likely to result in adverse medical results.

2.02-4 Drug Utilization Review Committee (DUR Committee) means an advisory committee to the Department of Human Services for the MaineCare Benefit and DEL Benefit, comprised of physicians and pharmacists who are licensed to prescribe or dispense drugs in Maine. The DUR Committee conducts drug utilization review for the Department.

2.02-5 MaineCare Benefits Manual (MBM) is the MaineCare policy set forth in Department of Human Services, 10-144, Chapter 101, MaineCare Benefits Manual.

2.02-6 Maine Maximum Allowable Cost (MMAC) is the maximum reimbursement amount that is established by the Maine Department of Human Services for certain multiple source drugs.

2.02-7 Medi-Span is a nationally recognized drug database. The Department uses this database to determine which drugs are defined as brand-name (single-source, cross-licensed or innovator) or generic (multiple-source) drugs for the purposes of calculating reimbursement.

2.02-8 National Drug Code (NDC) is a universal drug coding system for human drugs established by the Federal Food and Drug Administration, as set forth in 21 C.F.R 207. The FDA assigns each drug a unique identification number specifying the labeler/vendor, product, and package.

2.02 DEFINITIONS (cont.)

2.02-9 Non-Preferred Drugs are covered drugs that are not preferred drugs.

2.02-10 OBRA 90 is the Omnibus Budget Reconciliation Act of 1990 as amended.

2.02-11 Over-The-Counter Drug (OTC) is a drug that can be purchased without a prescription.

2.02-12 Participant is an individual who is eligible for and is receiving the DEL Benefit.

2.02-13 Pharmacy Provider is a corporation, association, partnership, or individual that either provides pharmacy services pursuant to a provider agreement with MaineCare or is related by ownership or control to an entity that provides MaineCare or DEL Benefit services, and is also a Medicare pharmacy provider.

2.02-14 Preferred Drugs are covered drugs that are clinically efficacious and which have a lower therapeutic category as determined by the Department after reviewing the recommendation of the Drug Utilization Review Committee.

2.02-15 Preferred Drug List (PDL) is a listing of covered drugs setting forth such information as their status as preferred or non-preferred, whether prior authorization may be required, step order, and any other information as determined by the Department to be helpful to participants, pharmacists, prescribers and other interested parties.

2.02-16 Therapeutic Category is a grouping of drugs by comparable therapeutic effect, as determined by the Department.

2.02-17 Usual & Customary Charge is the amount a pharmacy charges to individuals for prescription drugs for which those individuals do not have insurance coverage.

2.03 ELIGIBILITY

An individual is eligible to receive services as set forth in this Section if he or she meets the eligibility requirements established in 10-144 C.M.R. Chapter 333. Some participants may have restrictions on the type and amount of benefits they are eligible to receive under this Section.

2.04 REQUIREMENTS FOR PHARMACY PARTICIPATION IN DEL

A pharmacy that wishes to submit claims for payment under the Drugs for the Elderly Benefit must:

1. Comply with all provider and administrative process requirements set forth in Chapter 104, Section 1; and

2. Be enrolled as a MaineCare pharmacy provider.

2.05 BENEFITS

Only those drugs of manufacturers that have both a valid rebate agreement with the federal government pursuant to 42 U.S.C. § 1396r-8 and a DEL Rebate Agreement are covered in the DEL Benefit. In addition, drugs may be subject to prior authorization and the step order as set forth in this Section. The Department may refuse coverage for a drug when the prescriber cannot demonstrate medical necessity.

2.05-1 Basic Benefit

A. Covered Drugs

1. Prescription Drugs

The Basic benefit covers brand-name and generic drugs when administered for the following conditions and illnesses: heart disease, diabetes, high blood pressure, arthritis, chronic lung disease (including emphysema and asthma), anticoagulation, hyperlipidemia (high cholesterol), incontinence, thyroid disease, osteoporosis (bone density loss), Parkinson's disease, glaucoma, and multiple sclerosis/amyotrophic lateral sclerosis (Lou Gehrig’s Disease).

2. Over-The-Counter Drugs

Some over-the-counter drugs are covered in the DEL Benefit when the Department determines that they are both cost-effective and that they have a National Drug Code (NDC) number. These drugs will be approved only when the prescriber can demonstrate, with appropriate medical justification, that the use of these drugs is medically necessary. The Department may exclude from coverage drugs that are equivalent to drugs that are available over-the-counter.

B. Co-Payments

In the Basic benefit, the participant must pay a co-payment for services requested and rendered of 20% of the reimbursement amount as defined in Section 2.09, plus $2 per prescription.

2.05-2 Supplemental Benefit

A. Covered Drugs

The Supplemental benefit includes all drugs not covered in the Basic benefit, including those used to treat illnesses and

2.05 BENEFITS (cont.)

conditions not included in the Basic benefit of those manufacturers that have entered a federal rebate agreement and a DEL rebate agreement, as set forth above.

B. Co-Payments

Under the Supplemental benefit, participants must pay 100% of the MaineCare prescription rate for brand-name drugs, as set forth in Subsection 2.06 of this Section, minus $2 per prescription. For generic prescription drugs or medications, participant must pay 20% of the reimbursement rate as defined in Section 2.09 plus $2 per prescription.

2.05-3 Catastrophic Benefit

A. Covered Drugs

All drugs covered by either the Basic benefit or the Supplemental benefit are covered in the Catastrophic benefit.

B. Eligibility for the Catastrophic Benefit

A participant is eligible for the Catastrophic benefit once that participant has paid total co-payments in the DEL benefit of at least $1,000 between August 1 and July 31 of any year(s) in which the participant is eligible, provided that:

1. Only co-payments for those drugs that were included in the DEL Benefit on or before May 31, 2001 apply toward the Catastrophic benefit. A list of those drugs is available from the Department and on the Department's designated website; and

2. Only those co-payments that are tracked through the Department's automated pharmacy management information Point of Purchase System apply toward the Catastrophic benefit.

C. Co-Payments

After the participant has paid a total of $1,000 in co-payments as set forth in 2.05-3(B), the participant may purchase any drugs covered by either the Basic or Supplemental benefit by paying 20% of the reimbursement rate described in Section 2.09 until the next July 31.

2.05 BENEFITS (cont.)

2.05-4 Prior Authorization (PA)

A. Determining Which Drugs May Be Subject to Prior Authorization

The Department may require prior authorization for certain drugs in the DEL benefit as set forth in this sub-section.

In determining when prior authorization will be required, the Department will consider the recommendations of the DUR Committee. The determination to impose prior authorization will be based on the efficacy, safety, and net cost of any given drug and of the other drugs within the therapeutic category. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: the American Hospital Formulary Service Drug Information, the United States Pharmacopoeia-Drug Information, the DRUGDEX Information System, and American Medical Association Drug Evaluations. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at section 2.09 of this rule, as adjusted by any manufacturer rebates and or supplemental rebates to be paid to the Department for that drug. The department may not consider net cost when imposing prior authorization unless it determines that the drug to be subject to prior authorization has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose. The Department may also consider the indications for which the drug may be prescribed, where appropriate.

The Department may require prior authorization of any generic drug that has a net cost that is greater than the net cost of its brand-name version.

The Department, in consultation with the DUR Committee, may determine that the prior authorization requirement may be waived on a case-by-case basis for patients who are established on a drug that otherwise might be subject to prior authorization.

B. Process for Seeking Prior Authorization

When the Department requires prior authorization, the participant’s physician must complete and submit a written form, including any required attachments, documenting the medical necessity of the prescribed drug. The Department may seek information such as documentation of other measures that have been attempted to correct the risk/condition, the timeframe

2.05 BENEFITS (cont.)

in which those other measures were attempted, and the reason for failure. The prescriber is also required to submit documentation that other drugs in the same therapeutic category are contraindicated.

The Department will notify prescribers of the drugs that are subject to prior authorization and will provide them with forms for requesting authorization setting forth the information needed to approve a request. The list of drugs requiring PA and forms will be available on a website designated by the Department.

The requesting prescriber must complete the form applicable to the drug for which prior authorization is sought. The prescriber must send the completed form to the Department or its designee, as instructed by the Department, by mail, fax or by hand delivery.

During regular business days, the Department or its designee will respond to a completed request for prior authorization by fax, telephone or other telecommunications device within 24 hours of receipt.

In an emergency situation, including weekends, holidays, or any other time that the Department or its designee is not able to respond to a completed prior authorization request within 24 hours of receipt, the pharmacist is authorized to provide a one-time 96-hour supply of any prescribed drug that is a covered drug. The Department or its designee shall respond to a completed request under this subpart on the next regular business day. The provision of a 96-hour supply under this subpart does not relieve the prescriber of the obligation to complete and submit the prior authorization request form.

In the event that a prescriber fails to submit a completed form for a drug requiring prior authorization, the Department or its designee may authorize the pharmacy to dispense a one-time 34-day supply of the prescribed drug. The authorization of a 34-day supply under this provision does not relieve the prescriber of the obligation to complete and submit the prior authorization request form. If the prescriber has still failed to submit a completed prior authorization request by the end of the additional 34-day period, the Department will consider any refills of that prescription on a case-by-case basis.

The Department may require a provider to redo the prior authorization process every 12 months, or sooner if the participant's medical condition or the prior authorization criteria change.

2.05-5 Preferred Drug List

A. General

In order to facilitate appropriate utilization, the Department will establish a list of covered drugs, ordered by therapeutic category. Within each therapeutic category, the Department may designate some or all drugs as preferred on the basis of efficacy, safety, and net cost. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: The American Hospital Formulary Service Drug Information, the United States Pharmacopoeia-Drug Information, the DRUGDEX Information System, and American Medical Association Drug Evaluations. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at section 2.09 of this rule, as adjusted by any manufacturer rebates and or supplemental rebates to be paid to the Department for that drug. The department may not consider net cost when imposing prior authorization unless it determines that the drug to be subject to prior authorization has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose. This listing will be known as the Preferred Drug List or PDL.

In addition to the preferred/non-preferred designation, the PDL may include information such as generic name, strength/unit, National Drug Code identification number, and brand name.

All covered drugs, whether preferred or non-preferred, are available to any eligible participant for whom those drugs are medically necessary. Some drugs must have their medical necessity confirmed for a given participant through the prior authorization process before reimbursement will be provided by the Department.

B. Step Order

In addition to the preferred/non-preferred designations, the Department may assign some drugs on the PDL a further designation of preference within a therapeutic category. This further designation will be known as step order.

The step order is a means of reducing the need to obtain prior authorization. When a participant has been prescribed all drugs at a higher step(s) within a therapeutic category, the drug at the next lower step will automatically be reimbursed for that

2.05 BENEFITS (cont.)

participant without requiring prior authorization. Only drugs prescribed to the participant since enrollment and reflected in the Department's automated pharmacy management information Point of Purchase System will be considered in applying the step order.

C. Notification

The Department will post the PDL on the Department's designated web site. The Department will also provide quarterly notification of the drugs selected for placement on the PDL, and any other changes in the PDL. The list will be provided upon request to participants and providers who do not have Internet access.

2.06 FINANCIAL PARTICIPATION (CO-PAYMENT)

The Department requires each DEL participant to pay a co-payment for drugs, as set forth above. There are no exceptions. If the participant refuses to pay the co-payment, the pharmacy will deny the service.

2.07 ELIGIBILITY CARD

The Department of Human Services issues an eligibility card to each eligible participant enrolled in the DEL Benefit. A participant must present the eligibility card to the participating pharmacy upon request.

2.08 AMOUNT AND DURATION OF BENEFITS

The Department may stop reimbursing for covered drugs if, in any fiscal year, all the funds appropriated for DEL have been expended. When necessary, the Department will provide participants and participating pharmacies with prior notice of the date upon which reimbursement will cease.

2.09 REIMBURSEMENT

The Department will only reimburse participating pharmacies for drugs that are covered drugs as set forth above.

The DEL Benefit is the payor of last resort. If the participant has another prescription drug coverage plan, that plan must be billed first.

2.09 REIMBURSEMENT (cont.)

A. The Department may establish the Maine Maximum Allowable Cost (MMAC) for covered drugs, considering the following factors:

Multiple manufacturers;
Broad wholesale price span;
Availability of drugs to retailers at the selected cost;
High volume of utilization;
Bioequivalence or interchangability.

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B. ~~From July 1, 2003 through June 30, 2004, t~~The amount of reimbursement will be the lowest of the following:

1. The usual and customary charge;

2. The Average Wholesale Price minus ~~14~~15% plus a $2.35 professional fee; or

3. The Maine Maximum Allowable cost plus a $2.35 professional fee.

~~C. Beginning July 1, 2004, the amount of reimbursement will be the lowest of the following:~~
~~1. The usual and customary charge;~~
~~2. The Average Wholesale Price minus 13% plus a $3.35 professional fee; or~~
~~3. The Maine Maximum Allowable cost plus a $3.35 professional fee.~~

2.10 APPEALS

Each participant has the right to an administrative hearing to appeal any decision by the Department that adversely affects that participant's benefit. These appeal rights are set forth in Chapter 104, section 1.

2.11 BILLING INSTRUCTIONS

Participating pharmacies must bill in accordance with the Department's billing instructions set forth in the pharmacy's MaineCare agreement.